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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,911

01/29/2007

Peter Budtz

030427-0109

4642

22428 7590 12/28/2009  
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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,911	<b>Applicant(s)</b> BUDTZ ET AL.	
	<b>Examiner</b> SHERIDAN R. MACAULEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-54 is/are pending in the application.
- 4a) Of the above claim(s) 31, 50, 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-30, 32-49, 51 and 53 is/are rejected.
- 7) ☒ Claim(s) 38 and 43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/21/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 27-54 are pending.

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I (claims 27-30, 32-49, 51 and 53) and  $\text{Ca}(\text{OH})_2$  as the species of base in the reply filed on September 17, 2009 is acknowledged. The requirement for restriction is deemed to be proper and is therefore made final.
2. Claims 31, 50, 52 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups and species, there being no allowable generic or linking claim.
3. Claims 27-30, 32-49, 51 and 53 are examined on the merits in this office action.

### ***Information Disclosure Statement***

4. The information disclosure statement filed March 21, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The IDS has been placed in the application file, but the references that were not provided have not been considered.
5. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2)

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requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

6. Specifically, applicant has not included a legible copy of each foreign patent or each publication or that portion which caused it to be listed.

### ***Claim Objections***

7. Claim 38 is objected to because of the following informalities: The claim currently recites that "the conditions in step ii) is selected". This should be amended to recite "the conditions in step ii) are" or some other appropriate alternative. Appropriate correction is required.

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8. Claim 43 is objected to because of the following informalities: The claim currently recites that "a time period that at least last". This should be amended to recite " a time period that at least lasts" or some other appropriate alternative. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 36, 37, 40, 41, 42 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

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*Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 36, 37, 41 and 44 contain this type of language. Claim 36 contains the broad recitation "*Microdochium*", and the claim also recites "*M. nivale*" and "*M. nivale* CBS 100236" which are the narrower statements of the range/limitation. Claim 37 contains the broad recitation from "1 to 500 OXU per kg", and the claim also recites "5 to 500" which is the narrower statement of the range/limitation. Claim 40 contains the broad recitation "at least 5%", and the claim also recites "at least 15%", "at least 30%" and "at least 45%" which are the narrower statements of the range/limitation. Claim 41 contains the broad recitation "from about 3.0 to 6.9 and from 7.1 to about 9.0", and the claim also "from about 5 to 6.9 and from 7.1 to about 8" which is the narrower statement of the range/limitation. Claim 44 contains the broad recitation "from 30 minutes to 48 hours", and the claim also recites "from 1 hour to 36 hours" and "from 2 hours to 24 hours" which are the narrower statements of the range/limitation.

12. Also, claim 41 is rendered indefinite by the recitation of "at a pH of from about 3.0 to 6.9 and from 7.1 to about 9.0". This language renders the claim indefinite because it is unclear what pH range applicant intends to recite in the claim. Applicant could be intending to claim that the pH is within those ranges at two different times or in two different locations. If applicant intends to claim that the pH is within either of those ranges, applicant is advised to amend the claim to recite "at a pH of from about 3.0 to 6.9 or from 7.1 to about 9.0," or some other concise terminology.

13. Claim 42 is rendered indefinite by the term "when 95% of the desired conversion has been achieved. It is unclear what applicant intends by "the desired conversion" and

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how one of ordinary skill in the art would assess when 95% of this would be achieved.

For instance, the desired conversion could be 50%, 80% or 100%. Therefore, the metes and bounds of the claim would be unclear to one of ordinary skill in the art.

### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 27, 29, 30, 33-35, 38-41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullmann et al. (US 3,930,028). Claim 27 recites a process of obtaining increased yield and/or a reduced reaction time in enzymatic conversion of lactose to lactobionic acid, said process comprising: i) adding to a dairy substrate a carbohydrate oxidase, ii) incubating said dairy substrate under conditions allowing the carbohydrate oxidase to convert lactose to lactobionic acid iii) maintaining pH at a stable level during incubation by addition of a base, provided that when a strong base is added said stable level is not a pH of 7.0, and thereby obtaining said increased yield and/or reduced reaction time. Claim 29 recites the process according to claim 27 further comprising the step of re-using the carbohydrate oxidase added in step i) for a new batch. Claim 30 recites the process according to claim 27, wherein the base is a weak base. Claim 33 recites the process according to claim 27, wherein pH in step iii) is maintained by adding the base during a time period that is sufficient to obtain a degree

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of conversion of lactose to lactobionic acid that is at least 2.5% higher than in a comparative control process wherein pH is not maintained during incubation. Claim 34 recites the process according to claim 27, wherein the dairy substrate is milk, whey or fractions of whey or a lactose solution/suspension. Claim 35 recites the process according to claim 27, wherein the carbohydrate oxidase is a microbial carbohydrate oxidase. Claim 37 recites the process according to claim 27, wherein the amount of oxidase used is in the range from 0.1 to 1000 OXU per kg of dairy substrate. Claim 38 recites the process according to claim 27, wherein the conditions in step ii) is selected from the group consisting of temperature, addition of oxygen, amount and type of carbohydrate oxidase, amount and type of catalase and time. Claim 39 recites the process according to claim 38, wherein the temperature is in the range of 0 to 80 degrees C. Claim 40 recites the process according to claim 27, wherein pH in step iii) is maintained, by adequate addition of a base for a period of time sufficient to obtain a degree of conversion of lactose to lactobionic acid that is at least 5% higher than in a comparative control process where the only comparative difference is that during the incubation the pH is not maintained by adequate addition of a base. Claim 41 recites the process according to claim 27, wherein the pH is maintained, by adequate addition of a base, at a pH from about 3.0 to 6.9 and from 7.1 to about 9.0. Claim 44 recites the process according to claim 27, wherein the pH is maintained at the stable pH level as described herein for a time period from 30 minutes to 48 hours.

16. Ullmann teaches a process of treating a dairy substrate (a lactose solution) by adding to the substrate a carbohydrate oxidase (lactose oxidase, a microbial



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carbohydrate oxidase), incubating the substrate under conditions to reduce the amount of lactose, and maintaining the pH at a stable level during incubation by addition of a weak base (ammonium; col. 6, lines 18-24, col. 4, example 3). Since lactose oxidase catalyzes the conversion of lactose to lactobionic acid, the product of the process taught by the reference is lactobionic acid. The reference teaches improved levels of conversion of lactose (col. 4, example 3). The reference also teaches reusing the bacteria (which produce the carbohydrate oxidase) used in the process for use in a new batch (col. 2, lines 48-49). Since the pH of the process is maintained, the process would inherently operate at the rate of a pH-controlled process when compared to a non-pH controlled process. The reference teaches that the pH is maintained at a level between 6 and 7 and that the process may be operated at a pH of 6 (col. 6, lines 37-41). Ullmann teaches that the temperature is maintained between 25 degrees C and 30 degrees C for up to 48 hours (col. 6, lines 40-41, col. 4, example 3).

17. Therefore, Ullmann anticipates the limitations of the claims.

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 27, 29, 30, 33-44, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullmann et al. (US 3,930,028) in view of Lynglev (US 2003/0113405 A1). Claim 27 recites a process of obtaining increased yield and/or a reduced reaction time in enzymatic conversion of lactose to lactobionic acid, said process comprising: i) adding to a dairy substrate a carbohydrate oxidase, ii) incubating said dairy substrate under conditions allowing the carbohydrate oxidase to convert lactose to lactobionic acid iii) maintaining pH at a stable level during incubation by addition of a base, provided that when a strong base is added said stable level is not a

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pH of 7.0, and thereby obtaining said increased yield and/or reduced reaction time.

Claim 29 recites the process according to claim 27 further comprising the step of re-using the carbohydrate oxidase added in step i) for a new batch. Claim 30 recites the process according to claim 27, wherein the base is a weak base. Claim 33 recites the process according to claim 27, wherein pH in step iii) is maintained by adding the base during a time period that is sufficient to obtain a degree of conversion of lactose to lactobionic acid that is at least 2.5% higher than in a comparative control process wherein pH is not maintained during incubation. Claim 34 recites the process according to claim 27, wherein the dairy substrate is milk, whey or fractions of whey or a lactose solution/suspension. Claim 35 recites the process according to claim 27, wherein the carbohydrate oxidase is a microbial carbohydrate oxidase. Claim 36 recites the process according to claim 35, wherein the carbohydrate oxidase is a carbohydrate oxidase obtained from a fungus belonging to the genus *Microdochium*. Claim 37 recites the process according to claim 27, wherein the amount of oxidase used is in the range from 0.1 to 1000 OXU per kg of dairy substrate. Claim 38 recites the process according to claim 27, wherein the conditions in step ii) is selected from the group consisting of temperature, addition of oxygen, amount and type of carbohydrate oxidase, amount and type of catalase and time. Claim 39 recites the process according to claim 38, wherein the temperature is in the range of 0 to 80 degrees C. Claim 40 recites the process according to claim 27, wherein pH in step iii) is maintained, by adequate addition of a base for a period of time sufficient to obtain a degree of conversion of lactose to lactobionic acid that is at least 5% higher than in a comparative control process where

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the only comparative difference is that during the incubation the pH is not maintained by adequate addition of a base. Claim 41 recites the process according to claim 27, wherein the pH is maintained, by adequate addition of a base, at a pH from about 3.0 to 6.9 and from 7.1 to about 9.0. Claim 42 recites the process according to claim 27, wherein the pH is maintained at a stable pH from the beginning of the enzymatic reaction, when 95% of the desired conversion has been achieved the pH is allowed to drop to a desired level. Claim 43 recites the process according to claim 27, wherein the pH is maintained at the stable pH level for a time period that at least last until the oxygen level of the incubated dairy substrate has returned to more than 90% of the initial level. Claim 44 recites the process according to claim 27, wherein the pH is maintained at the stable pH level as described herein for a time period from 30 minutes to 48 hours. Claim 48 recites the process according to claim 27, wherein an optional purification results in a composition comprising at least 30% lactobionic acid or at least 90% lactobionic acid. Claim 49 recites the process according to claim 27, wherein a starter culture comprising lactic acid bacteria is included in the process and wherein the starter culture may be added to the dairy substrate before or after the oxidase is added. Claim 51 recites a process according to claim 27 as an integrated part of a food manufacturing process. Claim 53 recites the process according to claims 46, wherein essentially all of the suitable amount of oxygen required in step (ii) is obtained by extra addition of a suitable amount of hydrogen peroxide and wherein the catalase generates the required oxygen from the available hydrogen peroxide.

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22. Ullmann teaches a process of treating a dairy substrate (a lactose solution) by adding to the substrate a carbohydrate oxidase (lactose oxidase, a microbial carbohydrate oxidase), incubating the substrate under conditions to reduce the amount of lactose, and maintaining the pH at a stable level during incubation by addition of a weak base (ammonium; col. 6, lines 18-24, col. 4, example 3). Since lactose oxidase catalyzes the conversion of lactose to lactobionic acid, the product of the process taught by the reference is lactobionic acid. The reference teaches improved levels of conversion of lactose (col. 4, example 3). The reference also teaches reusing the bacteria (which produce the carbohydrate oxidase) used in the process for use in a new batch (col. 2, lines 48-49). Since the pH of the process is maintained, the process would inherently operate at the rate of a pH-controlled process when compared to a non-pH controlled process. The reference teaches that the pH is maintained at a level between 6 and 7 and that the process may be operated at a pH of 6 (col. 6, lines 37-41). Ullmann teaches that the temperature is maintained between 25 degrees C and 30 degrees C for up to 48 hours (col. 6, lines 40-41, col. 4, example 3). The reference does not teach the use of an enzyme from *Microdochium*, the amount of the enzyme that is added or that the enzyme is added before or after the starter culture.

23. Lynglev teaches a method for the production of a fermented dairy product wherein a carbohydrate oxidase is added to a dairy substrate and the substrate is incubated to allow conversion of lactose to lactobionic acid (abstract). The method teaches that a starter culture is added to the substrate before the oxidase is added (pp. 1-2, par. 20-22). In the process of Lynglev, the oxidase may be from a species of

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*Microdochium* (p. 1, par. 16-18). Although Lynglev discusses the use of 4-20 units of enzyme per 100 mL of dairy base, this amount would correspond to between 1 and 500 units per kg of dairy substrate (i.e., 20 units per 100 mL would correlate to 200 units per liter or per about 1 kg). At the end of the process of Lynglev, the pH is allowed to drop (p. 4, par. 72).

24. At the time of the invention, a method for the treatment of a dairy substrate using nearly the same process as is recited in the instant claims was known, as taught by Ullmann. It was also known that a method for the production of lactobionic acid could use the enzyme recited in the claims and that the product could be acidified at the end of the process. One of ordinary skill in the art would have been motivated to combine these methods because Lynglev is directed to the improvement of the process of dairy products by the conversion of lactose to lactobionic acid and Ullmann teaches that the oxidation of lactose is enhanced by controlling the pH of the reaction mixture. One would therefore recognize that the process of Ullmann could be modified using the enzyme and conditions of Lynglev. Although the references do not discuss the maintenance of the pH under the oxygen conditions recited in the claims, since Ullmann teaches the maintenance of pH under various conditions, it is expected that the maintenance under the claimed oxygen conditions would be performed or would have been achieved in the course of routine experimentation. One of ordinary skill in the art would have had a reasonable expectation of success in performing such a method because both references are directed to the fermentation of a dairy product using

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similar processes. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

25. Claims 27-29, 30, 32-44, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullmann et al. (US 3,930,028) in view of Lynglev (US 2003/0113405 A1) as applied to claims 27, 29, 30, 33-44, 48 and 49 above, and further in view of Koka (WO 02/089292 A1; cited in prior action). Claims 27, 29, 30, 33-44, 48 and 49 have been discussed above. Claim 28 recites the process according to claim 27 further comprising the step of purifying the lactobionic acid to obtain a substantially pure lactobionic acid product. Claim 32 recites the process according to claim 27, wherein the dairy substrate is milk and the base is  $\text{CaOH}_2$ .

26. The teachings of Ullmann and Lynglev have been provided in the rejections above. As discussed above, it would have been obvious to combine the teachings of the references to arrive at nearly all elements of the claimed invention. Neither reference, however, teaches the purification of lactobionic acid or the maintenance of the pH with  $\text{CaOH}_2$  (p. 18, lines 27-31).

27. Koka teaches a process comprising addition to a dairy substrate a carbohydrate oxidase, incubating the substrate under conditions allowing the oxidase to convert lactose to lactobionic acid, and maintaining pH at a stable level by addition of a base (abstract, p. 36, example 12). Koka teaches that the lactobionic acid may be produced and purified for subsequent use or produced directly in the dairy product (abstract, lines 7-16). The reference also teaches that the pH of such a product may be maintained with

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CaOH<sub>2</sub>. One of ordinary skill in the art would have been motivated to combine these teachings with the Ullmann and Lynglev references to arrive at the claimed invention because Koka teaches that lactobionic acid may be added separately in a cheesemaking process to acidify the cheese. Since Ullmann and Lynglev teach improved methods for the production of lactobionic acid, one would have recognized that the produced acid could have been separated and used in a different process. Furthermore, one would have been motivated to use CaOH<sub>2</sub> as a base in the process of Ullmann and Lynglev because Ullmann teaches the necessity of using a base to control the pH and Koka teaches that CaOH<sub>2</sub> is a compatible base in a cheesemaking process involving lactobionic acid. One of ordinary skill in the art would have had a reasonable expectation of success in performing such a method because the references are directed to the fermentation of a dairy product using similar processes. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

28. Claims 27, 29, 30, 33-48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullmann et al. (US 3,930,028) in view of Lynglev (US 2003/0113405 A1) as applied to claims 27, 29, 30, 33-44, 48 and 49 above, and further in view of Rand (Journal of Dairy Science, 1974, 58:1144-1150). Claims 27, 29, 30, 33-44, 48 and 49 are discussed above. Claim 45 recites the process according to claim 27, wherein a catalase is added in step (i) of the process in an amount that decreases the amount of hydrogen peroxide produced during conversion of lactose. Claim 46 recites



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the process according to claim 45, wherein the amount of catalase added is in an amount sufficient to obtain an at least 10% decrease in the concentration of hydrogen peroxide as compared to a control process where the only comparative difference is that catalase is not added. Claim 47 recites the process according to claims 45, wherein essentially all of the suitable amount of oxygen required in step (ii) is obtained by extra addition of a suitable amount of hydrogen peroxide and wherein the catalase generates the required oxygen from the available hydrogen peroxide.

29. The teachings of Ullmann and Lynglev have been provided in the rejections above. As discussed above, it would have been obvious to combine the teachings of the references to arrive at nearly all elements of the claimed invention. Neither reference, however, teaches addition of catalase and hydrogen peroxide in order to add oxygen to the reaction.

30. Rand teaches the addition of oxygen in the form of hydrogen peroxide in the presence of a catalase in order to regenerate the oxidase enzyme (see, for instance, p. 1144, col. 1). One of ordinary skill in the art would have been motivated to combine these teachings because the reference teaches that the addition hydrogen peroxide and catalase was an efficient system for the addition of oxygen throughout the milk substrate in a process for the oxidation of lactose. One would therefore have been motivated to add the components taught by Rand to the process of Ullmann and Lynglev and could reasonably expect the added oxygen to improve the rate of the reaction, since the reaction is oxygen-dependent. One of ordinary skill in the art would have had a reasonable expectation of success in performing such a method because

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the references are directed to the fermentation of a dairy product using similar processes. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

31. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Double Patenting***

32. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

33. Claims 27-30, 32-49, 51 and 53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 11/621819 in view of Ullmann et al. (US 3,930,028) and

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Lynglev (US 2003/0113405 A1). The claims of the copending application are directed to a method of making a lactobionate product that meets all of the limitation of claim 1 of the instant claims. Those elements of the claims under examination that are not disclosed in the copending application are taught by the cited references, as discussed above. The motivation to combine the method recited in the claims of the copending application and the references to arrive at the claimed process are discussed in the above rejections. Therefore, the claims of the instant application are rendered obvious and therefore unpatentable in view of the claims of the copending application and the cited references.

34. This is a provisional obviousness-type double patenting rejection.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651